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|---|-------------|----------------------|---------------------|------------------|
| 09/973,609  | 10/09/2001  | Shlomo Gabbay        | SHEP5010US          | 8158             |
| 26294   | 7590        | 12/28/2004           | EXAMINER            |                  |
| TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.<br>526 SUPERIOR AVENUE, SUITE 1111<br>CLEVEVLAND, OH 44114 |             |                      | PELLEGRINO, BRIAN E |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3738                |                  |

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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GROUP 3700

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/973,609

Filing Date: October 09, 2001

Appellant(s): GABBAY, SHLOMO

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Gary Pitzer  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 9/24/04.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

Claims 51 and 52 remain objected to.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 6/28/04 has not been entered.

The amendment after final rejection filed on 9/28/04 has been entered.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Appellant's brief includes a statement that claims 17,54-57,60 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8) *ClaimsAppealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) *Prior Art of Record***

|                |                               |                |
|----------------|-------------------------------|----------------|
| <b>5855601</b> | <b><i>Bessler et al.</i></b>  | <b>1-1999</b>  |
| <b>5549665</b> | <b><i>Vesely et al.</i></b>   | <b>8-1996</b>  |
| <b>5733267</b> | <b><i>Del Toro</i></b>        | <b>3-1998</b>  |
| <b>5851210</b> | <b><i>Torossian</i></b>       | <b>12-1998</b> |
| <b>6077296</b> | <b><i>Shokoohi et al.</i></b> | <b>6-2000</b>  |

**(10) *Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

Claims 18,19,53,54,56 are rejected under 35 U.S.C. 103(a) over Bessler et al.

This rejection is set forth in a prior Office Action, mailed on 4/27/04. Additionally, note that Fig. 14, shows an enclosure **103** and a body portion of the implanter or catheter **102** that has a greater diameter than the enclosure that is within the catheter. Also note that enclosure and body portion are "substantially coaxial" through the implanter.

Claim 17 is rejected under 35 U.S.C. 103(a) over Bessler et al. in view of Vesely et al. This rejection is set forth in a prior Office Action, mailed on 4/27/04.

Claims 2-16 are rejected under 35 U.S.C. 103(a) over Bessler et al. in view of Shokoohi et al. This rejection is set forth in a prior Office Action, mailed on 4/27/04.

Claims 50,55,60 are rejected under 35 U.S.C. 103(a) over Bessler et al. in view of Del Toro. This rejection is set forth in a prior Office Action, mailed on 4/27/04.

Claims 20,21,28,49,57 are rejected under 35 U.S.C. 103(a) over Bessler et al. in view of Torossian. This rejection is set forth in a prior Office Action, mailed on 4/27/04.

Claims 22-26 are rejected under 35 U.S.C. 103(a) over Bessler et al. in view of Torossian as applied to claim 20 above, and further in view of Shokoohi et al. This rejection is set forth in a prior Office Action, mailed on 4/27/04.

Claim 27 is rejected under 35 U.S.C. 103(a) over Bessler et al. in view of Torossian as applied to claim 20 above, and further in view of Vesely et al. This rejection is set forth in a prior Office Action, mailed on 4/27/04.

#### **(11) Response to Argument**

Applicant failed to submit an argument under the heading "Arguments" pointing out disagreements with the examiner's contentions. Applicant does not discuss the references applied against claims 20-28,49 explaining how the claims avoid the references or distinguish from them. Thus, the prior art properly rejects claims 20-28 and 49.

Applicant's arguments filed 9/24/04 have been fully considered but they are not persuasive with respect to claim 18. Applicant contends that the Bessler valve prosthesis cannot be substituted with a pulmonic valve. However, Applicant's

specification fails to provide any criticality as to what tissue is used for the claimed prosthesis, see for example page 6, lines 4,5. Additionally, at page 20, lines 10, 11 and page 23, lines 4,5, the disclosure gives an example of the type of tissue that is possible to use for replacing a pulmonic valve. Note the claims are directed to a product or apparatus, such that intended uses are irrelevant to patentability especially when there is no distinguishing structure. Also note that the claims do not even recite what type of valve the prosthesis is intended to replace. Applicant's representative contends the pulmonic valve has inherent structural features, but fails to point out where in the disclosure these distinguishing features are present. The attorney provides statements describing these particular features to distinguish the pulmonic valve from the aortic valve. However, MPEP 716(C) states: The arguments of counsel cannot take the place of evidence in the record. Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter. Therefore, these allegations cannot be considered to distinguish the rejection of claim 18 over Bessler.

Claim 54 is obvious over Bessler for the reasons mentioned above, because the body portion **102** clearly has a greater diameter than the enclosure **103**. Regarding claim 56, the body of the catheter and enclosure are clearly "substantially coaxial."

With respect to claim 17, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can

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only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, It is well known in the art that cloth coverings provide smoother surfaces over stent structures, in addition to providing suturing ability and a surface for tissue ingrowth to occur.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The combination of Bessler and Toro for the rejection of claim 50 was not to modify the catheter system as the arguments imply, but only to incorporate a handle since Bessler was silent about a handle on the catheter. It would be an obvious expedient to have a handle for any surgeon using a catheter when delivering apparatus within a patient's vascular system. The arguments for claim 60 are explained *supra* for the use of a pulmonic valve.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

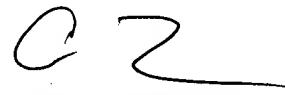
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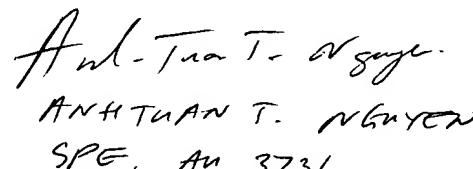
Respectfully submitted,

TC 3700, AU 3738  
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